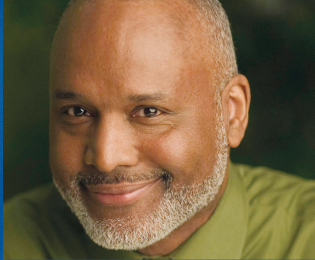
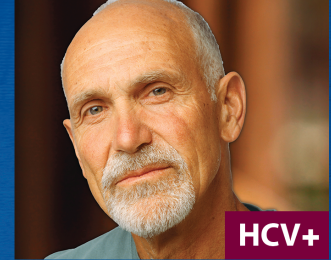


How to Apply for a CLIA Certificate of Waiver



HIV+



HCV+

Clinical Laboratory Improvement Amendments (CLIA) Background

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. A laboratory is defined as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. The Centers for Medicare and Medicaid Services (CMS) is charged with the implementation of CLIA, including laboratory registration, fee collection, surveys, surveyor guidelines and training, enforcement, approvals of PT providers, accrediting organizations and exempt states. The FDA is responsible for test categorization.



Completing the application form

Section 1 - General Information

- > The CLIA application form (CMS-116) can be obtained at the CMS website:

www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf.

You must have Adobe Acrobat Reader installed on your computer in order to view and print this document. A link on the CMS site has been provided for obtaining the free viewing software if it is not already installed on your computer system.

Name of Director

- > This person should be identified as the principle party responsible for overseeing testing programs, ensuring that facility personnel administering testing are fully trained, and documentation is maintained to meet CLIA standards. States deemed as "State Licensure" or "Exempt" may require additional accreditation within their individual states to qualify (e.g. medical director with licensed medical degree, etc.). Refer to state listing for the states that may apply.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0581

**CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)
APPLICATION FOR CERTIFICATION**

I. GENERAL INFORMATION

☒ Initial Application ☐ Survey
☐ Change in Certification Type
☐ Other Changes (Specify)

CLIA IDENTIFICATION NUMBER
Leave Blank for New Applications
_____ (If an initial application leave blank, a number will be assigned)

FACILITY NAME
The Family Center of PA

FEDERAL TAX IDENTIFICATION NUMBER
12-3456789

EMAIL ADDRESS

TELEPHONE NO. (Include area code) FAX NO. (Include area code)
(610)345-6789 (610)345-6788

FACILITY ADDRESS — Physical Location of Laboratory (Building, Floor, Suite
If applicable, Free Coupon/Certificate will be mailed to this Address unless
mailing address is specified)

MAILING/BILLING ADDRESS (If different from street address)
**The Family Center of PA
Attn: Accounts Payable**

NUMBER, STREET (No P.O. Boxes) CITY STATE ZIP CODE
123 East First Street - Suite 100 Reading PA 12345

NUMBER, STREET CITY STATE ZIP CODE
123 East First Street - Suite 100 Reading PA 12346

NAME OF DIRECTOR (Last, First, Middle Initial) FOR OFFICE USE ONLY
Taylor, John, S.

Date Received

II. TYPE OF CERTIFICATE REQUESTED (Check only one)

☐ Certificate of Waiver (Complete Sections I – VI and IX – X)

Section 2 - Type of Certificate

Certificate of

- > Check box indicated.

The following are the types of CLIA Certificates that may be obtained. All types of certificates permit testing with approved CLIA waived tests.

- **Certificate of Waiver (COW):** Issued to lab that performs only waived tests.
- **Certificate for Provider Performed Microscopy (PPM) procedures:** Issued to lab in which physician, midlevel practitioner or dentist performs specific microscopy procedures categorized as moderate complexity.
- **Certificate of Registration:** Issued to lab to conduct nonwaived (moderate and/or high complexity) testing until lab is determined to be in compliance with CLIA regulations.

II. TYPE OF CERTIFICATE REQUESTED (Check only one)

☒ Certificate of Waiver (Complete Sections I – VI and IX – X)

☐ Certificate for Provider Performed Microscopy Procedures (PPM) (Complete Sections I – X)

☐ Certificate of Compliance (Complete Sections I – X)

☐ Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes

☐ The Joint Commission ☐ AOA ☐ AABB
☐ CAP ☐ COLA ☐ ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA requirements. Proof of these requirements for the laboratory director must be submitted with the application.

- **Certificate of Compliance (COC):** Issued to lab that performs nonwaived (moderate and/or high complexity) testing once the State Dept. of Health determines lab is compliant with CLIA requirements.
- **Certificate of Accreditation (COA):** Issued to lab that performs nonwaived (moderate and/or high complexity) testing, and is based on an accreditation by organization approved by CMS (Centers for Medicare/Medicaid Services).

* All types are effective for two years.

Section 3 - Type of Laboratory

Facility Identification

- > This should be checked off from the description that best describes the type of facility and services provided.

III. TYPE OF LABORATORY (Check the one most descriptive of facility type)

<input type="checkbox"/> 01 Ambulance	<input type="checkbox"/> 11 Health Main. Organization	<input type="checkbox"/> 22 Practitioner Other (Specify)
<input type="checkbox"/> 02 Ambulatory Surgery Center	<input type="checkbox"/> 12 Home Health Agency	
<input type="checkbox"/> 03 Ancillary Testing Site in Health Care Facility	<input type="checkbox"/> 13 Hospice	<input type="checkbox"/> 23 Prison
<input type="checkbox"/> 04 Assisted Living Facility	<input type="checkbox"/> 14 Hospital	<input type="checkbox"/> 24 Public Health Laboratories
<input type="checkbox"/> 05 Blood Bank	<input type="checkbox"/> 15 Independent	<input type="checkbox"/> 25 Rural Health Clinic
<input checked="" type="checkbox"/> 06 Community Clinic	<input type="checkbox"/> 16 Industrial	<input type="checkbox"/> 26 School/Student Health Service
<input type="checkbox"/> 07 Comp. Outpatient Rehab Facility	<input type="checkbox"/> 17 Insurance	<input type="checkbox"/> 27 Skilled Nursing Facility/ Nursing Facility
<input type="checkbox"/> 08 End Stage Renal Disease Dialysis Facility	<input type="checkbox"/> 18 Intermediate Care Facility for Mentally Retarded	<input type="checkbox"/> 28 Tissue Bank/Repositories
<input type="checkbox"/> 09 Federally Qualified Health Center	<input type="checkbox"/> 19 Mobile Laboratory	<input type="checkbox"/> 29 Other (Specify)
<input type="checkbox"/> 10 Health Fair	<input type="checkbox"/> 20 Pharmacy	
	<input type="checkbox"/> 21 Physician Office	

Is this a shared lab? ☐ Yes ☐ No

IV. HOURS OF LABORATORY TESTING (List times during which laboratory testing is performed in HH:MM format)

Section 4 - Hours of Laboratory Testing

Hours of Operation

- > Indicate when testing services will be available at the test site. This may or may not mirror site location's operating hours.

IV. HOURS OF LABORATORY TESTING (List times during which laboratory testing is performed in HH:MM format)

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:		9:00	9:00	9:00	9:00	9:00	8:00
TO:		5:00	5:00	5:00	5:00	5:00	3:30

(For multiple sites, attach the additional information using the same format.)

V. MULTIPLE SITES (must meet one of the regulatory exceptions to apply for this provision)

Are you applying for the multiple site exception?
☐ No. If no, go to section VI. ☐ Yes. If yes, complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

1. Is this a laboratory that has temporary testing sites?
☐ Yes ☐ No

2. Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?
☐ Yes ☐ No
If yes, provide the number of sites under the certificate _____ and list name, address and test performed for each site below.

3. Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?
☐ Yes ☐ No
If yes, provide the number of sites under this certificate _____ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here ☐ and attach the additional information using the same format.

Section 5 - Multiple Sites

Multiple Locations

- > Most applications will respond "NO" to this question. Check off as indicated if applicable and immediately go to Section 6.

For applications that have multiple location sites, contact your local CMS office to ensure that the regulatory exceptions for this provision are met prior to completing this form. Additionally, Section 5 will require that each location's testing hours are identified.

V. MULTIPLE SITES (must meet one of the regulatory exceptions to apply for this provision)

Are you applying for the multiple site exception?
☒ No. If no, go to section VI. ☐ Yes. If yes, complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

1. Is this a laboratory that has temporary testing sites?
☐ Yes ☐ No

2. Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?
☐ Yes ☐ No
If yes, provide the number of sites under the certificate _____ and list name, address and test performed for each site below.

3. Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?
☐ Yes ☐ No
If yes, provide the number of sites under this certificate _____ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here ☐ and attach the additional information using the same format.

NAME AND ADDRESS/LOCATION	TESTS PERFORMED/SPECIALTY/SUBSPECIALTY
NAME OF LABORATORY OR HOSPITAL DEPARTMENT	
ADDRESS/LOCATION (Number, Street, Location if applicable)	
CITY, STATE, ZIP CODE	TELEPHONE NO. (Include area code)
NAME OF LABORATORY OR HOSPITAL DEPARTMENT	
ADDRESS/LOCATION (Number, Street, Location if applicable)	
CITY, STATE, ZIP CODE	TELEPHONE NO. (Include area code)

Form CMS-116 (10/10) 2

Section 6 - Waived Testing

Annual Test Volume

- > This number represents the total estimate number of tests that will be performed at the testing facility annually. Under CLIA Application of Waiver submission, the fee charged for a two-year certificate is \$150.00, regardless of the volume of CLIA waived tests conducted within a facility. Whereas, CLIA Certificates for Moderate Complexity and High Complexity are fee rendered by this number indicated as well as the type of testing performed as identified under Section 7.

In the next three sections, indicate testing performed and annual test volume.

VI. WAIVED TESTING
Identify the waived testing performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory.
e.g. (Rapid Strep, Acme Home Glucose Meter)
OraQuick ADVANCE Rapid HIV-1/2 Antibody Test; OraQuick HCV Rapid Antibody Test

Indicate the estimated **TOTAL ANNUAL TEST** volume for all waived tests performed **3,000**

☐ Check if no waived tests are performed

VII. PPM TESTING
Identify the tests performed

Skip Section 7 & 8 IF YOU ARE ONLY CONDUCTING WAIVED TESTING

Section 9 - Type of Control

Facility Overseer

- > Indicate which code closely identifies with your organization. This would be understood by how you are identified currently with the IRS for tax filing purposes.

IX. TYPE OF CONTROL

VOLUNTARY NONPROFIT	FOR PROFIT	GOVERNMENT
<input type="checkbox"/> 01 Religious Affiliation	<input type="checkbox"/> 04 Proprietary	<input type="checkbox"/> 05 City
<input checked="" type="checkbox"/> 02 Private Nonprofit		<input type="checkbox"/> 06 County
<input type="checkbox"/> 03 Other Nonprofit		<input type="checkbox"/> 07 State
(Specify)		<input type="checkbox"/> 08 Federal
		<input type="checkbox"/> 09 Other Government
		(Specify)

X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

Section 10 - Director Affiliation with Other Laboratories

Other Affiliations

- > Many identified Directors may have affiliations with other facilities and/or programs within each state. This section must be completed if the Director identified for this application has been registered to other site locations and/or organizations.

X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

CLIA NUMBER	NAME OF LABORATORY
41D1234567	Eastern Pennsylvania Crisis Center

ATTENTION: PLEASE CAREFULLY REVIEW ALL INFORMATION PROVIDED

Section 10 - Director Affiliation with Other Laboratories

Contractual Obligation

- > The Laboratory Director must sign and complete the application. By signing this application, the Director agrees to permit the Secretary, or any Federal officer or employee designated by the Secretary to inspect the laboratory, operations and all records at any reasonable time to determine applicants eligibility or continued eligibility for a CLIA certificate and continued compliance with CLIA requirements are met.

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION	
<p>Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.</p> <p>Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.</p>	
SIGNATURE OF OWNER/DIRECTOR OF LABORATORY (Sign in ink) John S. Taylor	DATE 03/02/2014
Form CMS-116 (10/10) 4	

Mail

Completed Application

- > Once the application is completed, it should be mailed directly to the local CMS office in your state. No check or money order should be sent at this time. The application is then entered into a national database. Within the next two (2) weeks, a bill with a detachable coupon will be mailed to the attention of the Director. Fees for a Certificate of Waiver for two years will be \$150.00. Detach the coupon and send along with payment to the address provided. Be sure to reference the assigned CLIA certificate number on your check should the coupon be lost or separated from payment.

CLIA Certificate of Waiver

- > Processing for a new certificate may take up to two months, however calling your local office may or may not yield information on the progress of your application. Your CLIA certificate number is established on your original invoice. Only once your payment is credited may you begin testing within your facility. The CLIA certificate will arrive approximately two (2) weeks following credited payment.

Renewal

- > Anticipate ten months prior to renewal date of your CLIA Certificate, a coupon voucher to arrive directed to the listed Director of the facility. Payment should be made by expected due date. Any changes from the original application should also be indicated. Once payment is received a renewal Certificate will be sent one month prior to the expiration date. If your CLIA waiver expires you must resubmit.

DISCLAIMER: Individual states may require additional fees and forms to be completed.

For additional information, contact your local CMS office.

State Survey Agencies (CLIA Contact List)

REGION I - Boston

CLIA LABORATORY PROGRAM
DEPARTMENT OF PUBLIC HEALTH
P. O. Box 340308
410 Capitol Avenue, MS#12 HSR
Hartford, CT 06134-0308
(860) 509-7400
FAX: (860) 509-7535
Contact: Lori Griffin

MASS. DEPT. OF PUBLIC HEALTH
BUREAU OF HEALTH CARE SAFETY AND
QUALITY
CLINICAL LABORATORY PROGRAM
99 Chauncy Street, 11th Floor
Boston, MA 02111
(617) 753-8438 or 8439
FAX: (617) 753-8240
Contact: Paul DiNatale

RI DEPARTMENT OF HEALTH
DIVISION OF FACILITIES REGULATION
3 Capitol Hill, Room 306
Providence, RI 02908
(401) 222-2721
FAX: (401) 222-3999
Contact: Floyd Salerno

CLIA PROGRAM
DIVISION OF LICENSING & REGULATORY
SERVICES
41 Anthony Avenue, Station #11
Augusta, ME 04333-0011
(207) 287-9339
FAX: (207) 287-9304
Contact: Dale Payne

HEALTH FACILITIES ADMINISTRATION
DEPARTMENT OF HEALTH
& HUMAN SERVICES
129 Pleasant Street
Concord, NH 03301
(603) 271-9048
FAX: (603) 271-4968
Contact: Rodney Bascom

State of Vermont – DAIL
Division of Licensing and Protection
103 South Main Street
Waterbury, VT 05671
(802) 871-3333
FAX: (802) 865-7701
Contact: K.C. Cushing

REGION II - New York

NEW JERSEY DEPARTMENT OF HEALTH
CLINICAL LABORATORY IMPROVEMENT SVC
P. O. Box 361
Trenton, NJ 08625-0361
(609) 406-6824
FAX: (609) 292-0424
Contact: Bhavna Patel

For Physician Office Laboratories in New York:
STATE OF NEW YORK DEPARTMENT OF HEALTH
PHYSICIAN OFFICE LABORATORY
EVALUATION PROGRAM
Empire State Plaza
P. O. Box 509
Albany, NY 12201-0509
(518) 485-5352
Contacts: Thomas L. Lipinski

For All Other Laboratory Facility Types in New York:
CLINICAL LABORATORY EVALUATION PROGRAM
Empire State Plaza
P. O. Box 509
Albany, NY 12201-0509
(518) 485-5378
Contacts: Stephanie Shulman

COMMONWEALTH OF PUERTO RICO
PUERTO RICO HEALTH DEPARTMENT
OFFICE OF CERTIFICATION & LICENSURE
1090 Marginal Ruiz Soler
Bayamón PR 00961-7329
(787) 765-2929 Ext. 4738
FAX: (787) 781-2088
Contact: Julia Colón

**LABORATORIES LOCATED IN THE VIRGIN ISLANDS
SHOULD CONTACT THE NY REGIONAL OFFICE**

DHHS/CMS/DSC/CLIA
CLIA Program
26 Federal Plaza Room 37-130
New York, NY 10278
(212) 616-2478
FAX: (443) 380-5171
Contact: Carmelita O. Ragaza

REGION III - Philadelphia

DELAWARE STATE PUBLIC
HEALTH LABORATORY
Timothy Smith
30 Sunnyside Road
Smyrna, DE 19977
(302) 223-1392
FAX: (302) 653-2877
Contact: Timothy Smith

DC DEPARTMENT OF HEALTH
Health Regulations and Licensing Administration
Health Facilities Division - Laboratory Services
899 North Capitol Street, NE-2nd Floor
Washington, DC 20002
(202) 727-1740
FAX: (202) 442-9431
Contact: Semret Tesfaye

MARYLAND DEPARTMENT OF HEALTH
& MENTAL HYGIENNE
OFFICE OF HEALTH CARE QUALITY- LABS
Bland Bryant Building
Spring Grove Hospital Center
55 Wade Avenue
Catonsville, MD 21228
(410) 402-8025
FAX: (410) 402-8213
Contact: Paul Celli

PENNSYLVANIA DEPARTMENT OF HEALTH
BUREAU OF LABORATORIES
110 Pickering Way
Exton, PA 19341
(610) 280-3464
FAX: (610) 594-9763
Contact: Mary A. McCormick B.S. M.S.Ed

VIRGINIA DEPARTMENT OF HEALTH
OFFICE OF LICENSURE AND CERTIFICATION
9600 Mayland Drive, Suite 401
Richmond, VA 23233
(804) 367-2107
FAX: (804) 527-4504
Contact: Sarah Pendergrass

WEST VIRGINIA DEPARTMENT OF HEALTH
OFFICE OF LABORATORY SERVICES
167 11th Avenue
South Charleston, WV 25303-1137
(304) 558-3530, extension 2103
FAX: (304) 558-2006
Contact: Jerry Gross

REGION IV - Atlanta

ALABAMA DEPARTMENT OF PUBLIC HEALTH
DIVISION OF HEALTH CARE FACILITIES
CLIA PROGRAM,
P.O. Box 303017
Montgomery, AL 36130-3017
(334) 206-5120
Contact: Faye Allen

STATE OF FLORIDA
AGENCY FOR HEALTH CARE ADMINISTRATION
LABORATORY LICENSING UNIT
2727 Mahan Drive, Mail Stop 32
Tallahassee, FL 32308
(850) 412-4500
FAX: (850) 410-1511
Contact: Patty Lewandowski

GEORGIA DEPARTMENT OF COMMUNITY HEALTH
HEALTHCARE FACILITY REGULATION DIVISION
DIAGNOSTIC SERVICES UNIT
2 Peachtree Street, N.W., Suite 31-447
Atlanta, GA 30303-3142
(404) 657-5558
FAX: (404) 463-4398
Contact: Nancy Spradlin

KENTUCKY CLIA PROGRAM
Office of Inspector General
275 E Main Street 5E-A
Frankfort, KY 40621
(502) 564-7963 Ext. 3298
FAX: (502) 564-6546
Contact: Mary Pollard

LICENSURE AND CERTIFICATION/CLIA
MISSISSIPPI DEPARTMENT OF HEALTH
P. O. Box 1700
Jackson, MS 39215-1700
(601) 364-1115
Contact: Theresa Irwin

State Survey Agencies (CLIA Contact List) continued

NORTH CAROLINA DEPARTMENT
OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION/
CLIA CERTIFICATION
2713 Mail Service Center
Raleigh, NC 27699-2713
(919) 855-4620
FAX: (919) 733-0176
Contact: Azzie Conley

SOUTH CAROLINA DEPARTMENT OF HEALTH
& ENVIRONMENTAL CONTROL
BUREAU OF CERTIFICATION/ HEALTH
REGULATION
2600 Bull Street
Columbia, SC 29201
(803) 545-4291
FAX: (803) 545-4563
Contact: Lakeisha N. Wright

TENNESSEE HEALTH CARE FACILITIES
665 Mainstream Drive
Nashville, TN 37243
(615) 741-7023
FAX: (615) 532-2700
Contact: Will Campbell

REGION V - Chicago

ILLINOIS DEPARTMENT OF PUBLIC HEALTH
DIVISION OF HEALTH CARE FACILITIES
& PROGRAMS
525 W Jefferson Street
Fourth Floor
Springfield, IL 62761
(217) 782-6747
FAX: (217) 782-0382
Contact: Jena Baumann

INDIANA STATE DEPARTMENT OF HEALTH
DIVISION OF ACUTE CARE SERVICES
2 North Meridian Street, Room 4A
Indianapolis, IN 46204
(317) 233-7502
FAX: (317) 233-7157
Contact: Lorraine Switzer

MICHIGAN DEPARTMENT OF LICENSING AND
REGULATORY AFFAIRS (LARA)
BUREAU OF HEALTH CARE SERVICES
LABORATORY IMPROVEMENT SECTION
611 W. Ottawa Street
P. O. Box 30664
Lansing, MI 48909
(517) 241-2645
FAX: (517) 241-3354
Contact: Michelle Roepke, BS, MT (ASCP)

MINNESOTA DEPARTMENT OF HEALTH
CLIA PROGRAM
3333 West Division Street, Suite 212
St. Cloud, MN 56301-4557
(651) 201-4120
Contacts: Kelly Siegel

OHIO DEPARTMENT OF HEALTH
LABORATORY CLIA LABORATORY PROGRAM
246 N. High Street, 3rd Floor
Columbus, OH 43215
(614) 644-1845
FAX: (614) 564-2478
Contact: Shannon Richey

WISCONSIN DEPARTMENT OF HEALTH SERVICES
DIVISION OF QUALITY ASSURANCE
CLINICAL LABORATORY SECTION
1 W. Wilson Street
P. O. Box 2969
Madison, WI 53701-2969
(608) 266-7485
FAX: (608) 264-9847
Contact: Angela Mack

REGION VI - Dallas

HEALTH FACILITY SERVICES Slot H9
ARKANSAS DEPARTMENT OF HEALTH
AND HUMAN SERVICES
5800 West 10th Street, Suite 400
Little Rock, AR 72204-9916
(501) 661-2201
FAX: (501) 280-4930
Contact: Liz Davis

DEPARTMENT OF HEALTH & HOSPITALS
HEALTH STANDARDS SECTION
CLIA PROGRAM
602 North 5th Street, 2nd Floor
Baton Rouge, LA 70802
(225) 342-9324
Fax: (225) 342-9349
Contact: Staci de León

HEALTH FACILITY LICENSING
AND CERTIFICATION BUREAU
Bank of the West Building
5301 Central Avenue NW, Suite 400
Albuquerque, NM 87108
(505) 222-8646
Fax: (505) 841-5834
Contact: Julie Aragon

OKLAHOMA STATE DEPARTMENT OF HEALTH
PROTECTIVE HEALTH SERVICES
MEDICAL FACILITIES
1000 NE 10th Street
Oklahoma City, OK 73117-1299
(405) 271-6576
FAX: (405) 271-1308
Contact: Karla Cason

TEXAS DEPARTMENT OF STATE
HEALTH SERVICES
FACILITY LICENSING GROUP (MC 1979)
P. O. Box 149347
Austin, TX 78714-9347
(512) 834-6792
Contact: Kaimy Chappell

REGION VII - Kansas City

IOWA CLIA LABORATORY PROGRAM
STATE HYGIENIC LABORATORY
University of Iowa Research Park
2490 Crosspark Road
Coralville, IA 52241
(319) 335-4500
FAX: (319) 335 4174
Contact: Nancy Grove, CLIA Compliance Manager

KANSAS DEPARTMENT OF HEALTH
& ENVIRONMENT
CLIA LABORATORY CERTIFICATION
6810 SE Dwight Street
Topeka, KS 66620
(785) 296-0096
FAX: (785) 296 1638
Contact: Ruby Brower

MISSOURI CLIA LABORATORY PROGRAM
DEPARTMENT OF HEALTH & SENIOR SVCS
Bureau of Outpatient Healthcare
3418 Knipp Drive, Suite D
P. O. Box 570
Jefferson City, MO 65102
(573) 751-6318
FAX: (573) 526 3621
Contact: Pam Campbell

NEBRASKA STATE HEALTH & HUMAN SERVICES
LICENSURE UNIT-DIVISION OF PUBLIC HEALTH
Office of Acute Care Facilities
P. O. Box 94986
Lincoln, NE 68509-4986
(402) 471-3484
Contact: Diana Meyer

REGION VIII - Denver

COLORADO DEPARTMENT OF PUBLIC HEALTH
& ENVIRONMENT
LABORATORY SERVICES DIVISION
8100 Lowry Blvd.
Denver, CO 80230-6928
(303) 692-3681
FAX: (303) 344-9965
Contact: Jeff Groff

MONTANA CLIA PROGRAM - DIVISION
OF QUALITY ASSURANCE - DEPARTMENT
OF PUBLIC HEALTH & HUMAN SERVICES
2401 Colonial Drive, 2nd Floor
P. O. Box 202953
Helena, MT 59620-2953
(406) 444-2099
FAX: (406) 444-3456
Contact: Joyce Shepard

NORTH DAKOTA DEPARTMENT OF HEALTH
DIVISION OF HEALTH FACILITIES
600 East Boulevard Avenue/DEPT 301
Bismarck, ND 58505-0200
(701) 328-2352
FAX: (701) 328-1890
Contact: Bridget Weidner

SOUTH DAKOTA DEPARTMENT OF HEALTH
OFFICE OF HEALTH CARE FACILITIES
LICENSURE AND CERTIFICATION
615 E. 4th Street
Pierre, SD 57501-1700
(605) 773-3694
FAX: (605) 773-6667
Contact: Connie Richards

UNIFIED STATE LABORATORIES:PUBLIC HEALTH
BUREAU OF LABORATORY IMPROVEMENT
4431 South 2700 West
Taylorsville, UT 84129
(801) 965-2531
FAX: (801) 965-2544
Contact: Jan Case

HEALTHCARE LICENSING AND SURVEYS
6101 Yellowstone Road, Suite 186C
Cheyenne, WY 82002
(307) 214-4049
FAX: (307) 777-7127
Contact: Dianne Whitlock

REGION IX - San Francisco

ARIZONA DEPARTMENT OF HEALTH
SERVICES
DIVISION OF PUBLIC HEALTH SERVICES
Office of Laboratory Licensing and Certification
250 N. 17th Avenue
Phoenix, AZ 85007
(602) 364-0726
FAX: (602) 364-0759
Contact: Denise Barbeau

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
DIVISION OF LABORATORY SERVICES
LABORATORY FIELD SERVICES
320 West 4th Street, Suite 890
Los Angeles, CA 90013-2398
(213) 620-6160
FAX: (213) 620-6565
Contact: Donna McCallum, Examiner III

HAWAII DEPARTMENT OF HEALTH
CLIA Program
601 Kamokila Blvd., Room 395
Kapolei, HI 96707
(808) 692-7420
FAX: (808) 692-7447
Contact: Susan O. Naka

FOR LABS IN AMERICAN SAMOA, GUAM, SAIPAN, ROTA OR TINIAN (The Commonwealth of the Northern Mariana Islands; CNMI) CONTACT REGIONAL OFFICE IX, SAN FRANCISCO

DHHS/CMS/DCS/CLIA
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707
(415) 744-3696
FAX: (415) 744-2692

STATE OF NEVADA DEPARTMENT OF HEALTH
AND HUMAN SERVICES
HEALTH DIVISION
BUREAU OF HEALTH CARE QUALITY & COMPLIANCE
727 Fairview Dr., Ste E
Carson City, NV 89701-5493
(775) 684-1060
FAX: (775) 684-1073
Contact: Vicki Estes, MT (ASCP), Supervisor Med Lab Svcs.

REGION X - Seattle

HSQA/IIO-LABORATORY QUALITY ASSURANCE
20425 72nd Ave S, Suite 310
Kent, WA 98032
(253) 395-6745
FAX: (253) 395-6365
Contact: Susan Walker, Program Manager

OREGON HEALTH AUTHORITY
OREGON STATE PUBLIC HEALTH DIVISION
LABORATORY COMPLIANCE SECTION (LCS)
3150 NW 229th Avenue, Suite 100
Hillsboro, OR 97124-6536
(503) 693-4126
FAX: (503) 693-5602
Contact: Stephanie B. Ringsage

LABORATORY IMPROVEMENT SECTION
IDAHO BUREAU OF LABORATORIES
2220 Old Penitentiary Road
Boise, ID 83712-8299
(208) 334-2235 x245
FAX: (208) 334-4067
Contact: Katey Anderson

ALASKA CLIA PROGRAM
ALASKA STATE PUBLIC HEALTH LABORATORY
5455 Dr. Martin Luther King Jr. Avenue
Anchorage, AK 99507
(907) 334-2112
FAX: (907) 334-2161
Contact: Katherine Ross

CLIA Important Information

State Exemption

- > Any laboratory located in a state that has a CMS approved laboratory program is exempt from CLIA certification. Currently, there are two states with approved programs: Washington and New York. New York has a partial exemption; therefore, if your laboratory is located in that state, contact the New York State Agency concerning your need for a CLIA certificate.

Additions or Changes to Issued Certificates

- > During the two-year certificate period, information supplied on the original certificate application may change (e.g., lab director, add-on site location, etc). It is important that this information be communicated in a prompt manner to the local State Reporting office. The local states maintain the database for each issued certificate within the state. For questions concerning changes to the current certificate status, it is best to contact your local CMS office for clarification. Most often a simple letter is all that is required. This will be kept on file at the state office. A new certificate **will not** be issued reflecting these changes. Only upon renewal application will the changed information be indicated.

Facility Inspections

- > The local state offices of CMS inspect facilities from time to time to monitor and ensure that each is operating under the CLIA guidelines. While these inspections are not punitive in nature, inspectors will check to see that Manufacturers' Guidelines are followed within each facility. Additionally, reported complaints in the field will prompt a mandatory inspection of any facility. A report will be written for both random and mandated inspections that will advise any inconsistencies and recommendations to bring a facility up to compliance. Timelines for compliance adherence will be established. What can this mean potentially to a CLIA waived testing site? If a second follow-up inspection reveals that conformance has not been established, the local CMS office can cease CLIA testing operations for a given time to that facility or site until conformance has been satisfactorily met. Similarly, if additional complaints are filed against the facility, CLIA certification can be permanently revoked and punitive action can take place dependent on the nature of the complaint.

